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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/633,145	08/04/2000	Chinnappa Kodira	CL000747	3253

7590 05/09/2002

Celera Genomics Corp.
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EXAMINER
WEGERT, SANDRA L

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 05/09/2002 14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n No.	Applicant(s)	
	09/633,145	KODIRA ET AL.	
	Examiner	Art Unit	
	Sandra Wegert	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,8,9,13 and 24-29* is/are pending in the application.

4a) Of the above claim(s) *13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,8,9 and 24-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *4,8,9,13 and 24-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The amendment filed 19 April 2002 (Paper No. 13) has been entered. Claims 1-3, 5-7, 10-12, and 14-23 are canceled. Claim 13 was withdrawn by the examiner. Claims 4, 8, 9, and 24-29 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections/Rejections

Withdrawn Objections and/or Rejections

Title

The objection to the title as set forth at p. 3 of the previous Office Action (Paper No. 11, 19 Dec., 2001) is *withdrawn* in view of the amendment which introduced a new title (Paper No. 13, 19 April, 2002).

Sequence Rules The objection to the disclosure for sequence rules as set forth at p. 3-4 of the previous Office Action (Paper No. 11, 19 Dec., 2001) is *withdrawn* in view of the amendment which introduced SEQ ID NO's into Figures 1-3 (Paper No. 13, 19 April, 2002).

Maintained Objections and/or Rejections

35 USC § 112, second paragraph-indefiniteness.

The rejection of Claim 24 because the specification does not teach how to recombinantly produce a polypeptide from the complementary nucleic acid as set forth at p. 9 of the previous Office Action (Paper No. 11, 19 Dec., 2001) is *maintained* because Claim 24 still refers to the polynucleotides of Claim 4a)-4d).

35 U.S.C. § 101/112, first paragraph-, Lack of Utility, Enablement.

Claims 4, 8, 9, and 24-29 are rejected under 35 U.S.C. 101, as lacking utility. The reasons for this rejection under *35 U.S.C. § 101* are set forth at pp. 4-9 of the previous Office Action (Paper No. 11, 19 Dec., 2001). Claims 4, 8, 9, and 24-29 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth in the previous Office Action (Paper No. 11, 19 Dec., 2001), one skilled in the art clearly would not know how to use the claimed invention.

The claims are directed to a nucleotide that encodes a polypeptide that possesses approximately 45% homology to known G-protein coupled receptors, such as Human *GPCR 58* (Lee, et al, 2000, Accession No. AF112460) and *GPCR 57* (Lee, et al, 2000, Accession No.

AF112460). As discussed in the previous Office Action (p. 5), no well-established utility exists for newly isolated complex biological molecules. The specification does not disclose experiments that impart *any* function for the putative receptor polypeptide encoded by the claimed nucleotide in the context of the cell or organism. The specification does not teach the skilled artisan how to use the receptor peptide for any unique or specific purpose. For example, there is no disclosure of the use of ligands of the receptor, or changes in the physiology of transfected cells, or the phenotypes of "knock-in" or "knock-out" organisms, or second-messenger assays, or of diseases caused by an overactivity or underactivity of the receptor. The skilled artisan is not provided with sufficient guidance to use the claimed polynucleotide for any purpose.

Applicants argue (page 7, for example, Paper No. 13, 19 April, 2002) that the nucleotide of the instant Specification encodes a G-protein coupled receptor, and that homology of the disclosed polypeptide with a class of proteins already having utility shall impart sufficient utility on the novel polypeptide and on the polynucleotide encoding it. However, the polypeptide of the Instant Specification and the polynucleotide encoding are, as yet, unidentified molecules. It possesses only low/moderate homology to known G-protein coupled receptors-- for example, GPCR58, which *itself* is yet uncharacterized (Lee, et al, 2000, Accession No. AF112460). Applicants further argue against the Utility/Enablement rejection by discussing the usefulness of receptor proteins as pharmacological targets (p. 6, last paragraph, Paper No. 13, 19 April, 2002). In fact, specific pharmacological data is precisely the type of evidence that would serve to enable the instant invention. For example, an enabling disclosure might identify ligands which bind

specifically to the Applicants' GPCR, and give evidence of receptor transduction after agonist binding.

Despite the Applicant's arguments (p. 5, last paragraph, Paper No. 13, 19 April, 2002) the Utility Guidelines make clear that the usefulness of new polynucleotides does not include "entry point" and speculative experiments (Federal Register, 2001, 66: 1094). There is no evidence that the protein disclosed in the instant Specification functions as a G-protein coupled receptor. However, even if it were established as such, additional specific functional assays would be needed since this family of proteins is very large and enormously varied (Ji, et al, 1998, JBC, 273:17299). Even closely-related family members sometimes work very differently and have different specific functions in the organism (Ji, et al, 1998, p. 17302, 3rd paragraph). While it is true that GPCR proteins have some structural features in common, this family of transmembrane receptors is noticeable for its *lack* of high homology of amino acid sequence (Probst, et al, 1992, DNA and Cell Biol., 11:1-20)—except, for example, in membrane spanning α-helices where the amino acid composition is constrained by hydrophobic forces (Probst, et al, 1992, DNA and Cell Biol., 11:1-20). Agonist binding sites, for example, show very low percent correspondence (Probst, et al, 1992, DNA and Cell Biol., 11:1-20, Fig. 2, page 4). And, despite the fact that intracellular transduction mechanisms converge (e.g., binding of only a limited numbers of G-proteins), the intracellular binding sites also bear very low homology (Probst, et al, 1992, DNA and Cell Biol., 11:1-20, Fig 2, pages 8 and 9).

One skilled in the art would not know the utility and function of the polypeptide disclosed in the instant disclosure, even if it *were* a G-protein coupled receptor because, as discussed in the related art above and the specification of the instant application (pp. 2-9), G-

protein-coupled receptors mediate hundreds or thousands of physiological functions involving cell-to-cell communication as the initial event

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The

examiner can normally be reached Monday - Friday from 8:30 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SLW

5/2/02

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER